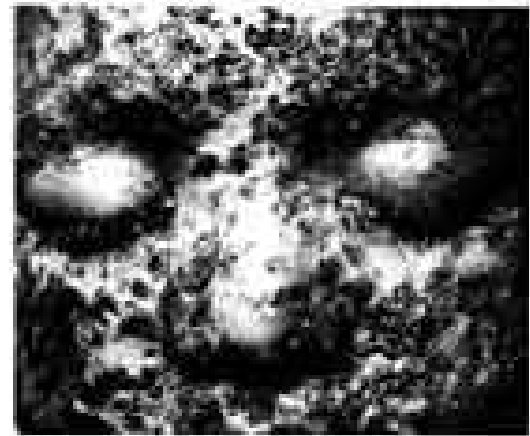


**Department of
Defense
Individual
Briefing**

*Engler Modified 17 Dec
2002*





Key Messages

1. Smallpox is a deadly disease that threatens the health of service members, health care workers and those involved in emergency preparedness and homeland defense.
2. Smallpox vaccine prevents smallpox, but requires very careful use to prevent serious side effects.
3. Screening for vaccine contraindications and prevention of complications in secondary contacts are critical to the success of vaccination delivery.
4. Vaccination procedure and what to expect
5. Preserving the health and safety of our people are our top concerns.

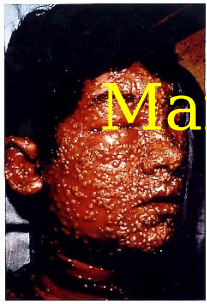




Threat

1. **Smallpox is a deadly disease that threatens the health of service members, health care workers and those involved in emergency preparedness.**
- **Smallpox is a contagious disease that spreads from one person to another.**
 - **Smallpox killed millions of people over many centuries, before being eradicated.**
 - **Terrorists or governments hostile to US may have or could obtain the smallpox (variola) virus.**
 - **A smallpox outbreak would significantly affect military readiness and the War on Terrorism.**





Managing The Threat

2. As a bioterrorism agent, smallpox would disrupt military missions and homeland defense.

- **Smallpox is a serious disease that can kill, blind or disable a large number of people of all ages.**
- **Medical care for patients with smallpox is complex and intensive, rapidly exhausting available resources.**
- **The disease causes permanent scarring in those who survive, particularly in the face.**
- **Immune (already vaccinated) military personnel, health care workers, and**





Vaccine

3. Smallpox vaccine is effective against smallpox, but requires very careful use to prevent serious side effects.

- World Health Organization (WHO) used this vaccine to eliminate natural smallpox disease
 - 95% of people are protected within 10 days
 - Solid protection for 3 to 5 years or longer
 - Partial protection lasts longer
 - But people need to be revaccinated if too much time has passed (≥ 10 years)
 - Can protect if given 3-5 days after exposure
- Contains vaccinia virus, cannot cause smallpox





Promoting Vaccine Safety

FDA Licensed Vaccine Available in 2002

- Live virus vaccine used 30 years ago
 - Dryvax® used in US during smallpox era
- Licensure and CDC/ACIP review of vaccine use
 - Focused on avoidance of vaccination in those with risk factors for serious complications due to the vaccine
 - Screening for contraindications, precautions and measures to prevent vaccine risk for close contacts stressed in program development



In the event of a smallpox outbreak however, there are no absolute contraindications

The Vaccination Process



The Needle - 1.6 mcl



Puncture x 3 or X 15





Expected & Side Effects

- Expected: A red blister turns white 6 to 8 days after vaccination. Then it will turn to a scab

This shows successful vaccination

second vaccination (no take)

Most people experience normal, mild reactions, such as sore arm, fever, headache, body ache, or fatigue

Symptoms peak 8-12 days after vaccination

Primary Vaccination Site Reaction



Day 4



Day 7



Day 14



Day 21

1 cm=one-half inch

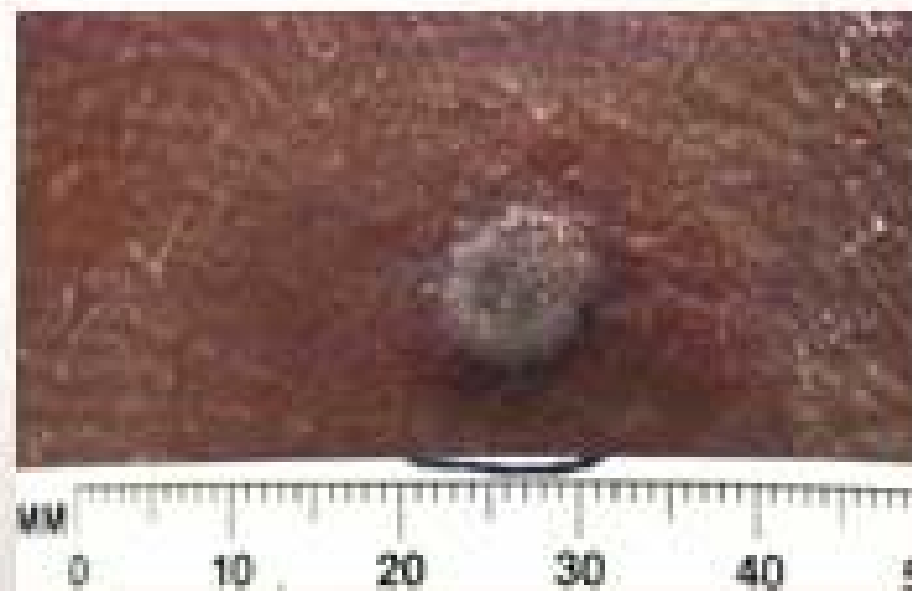
Source:
CDC



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Normal Reaction



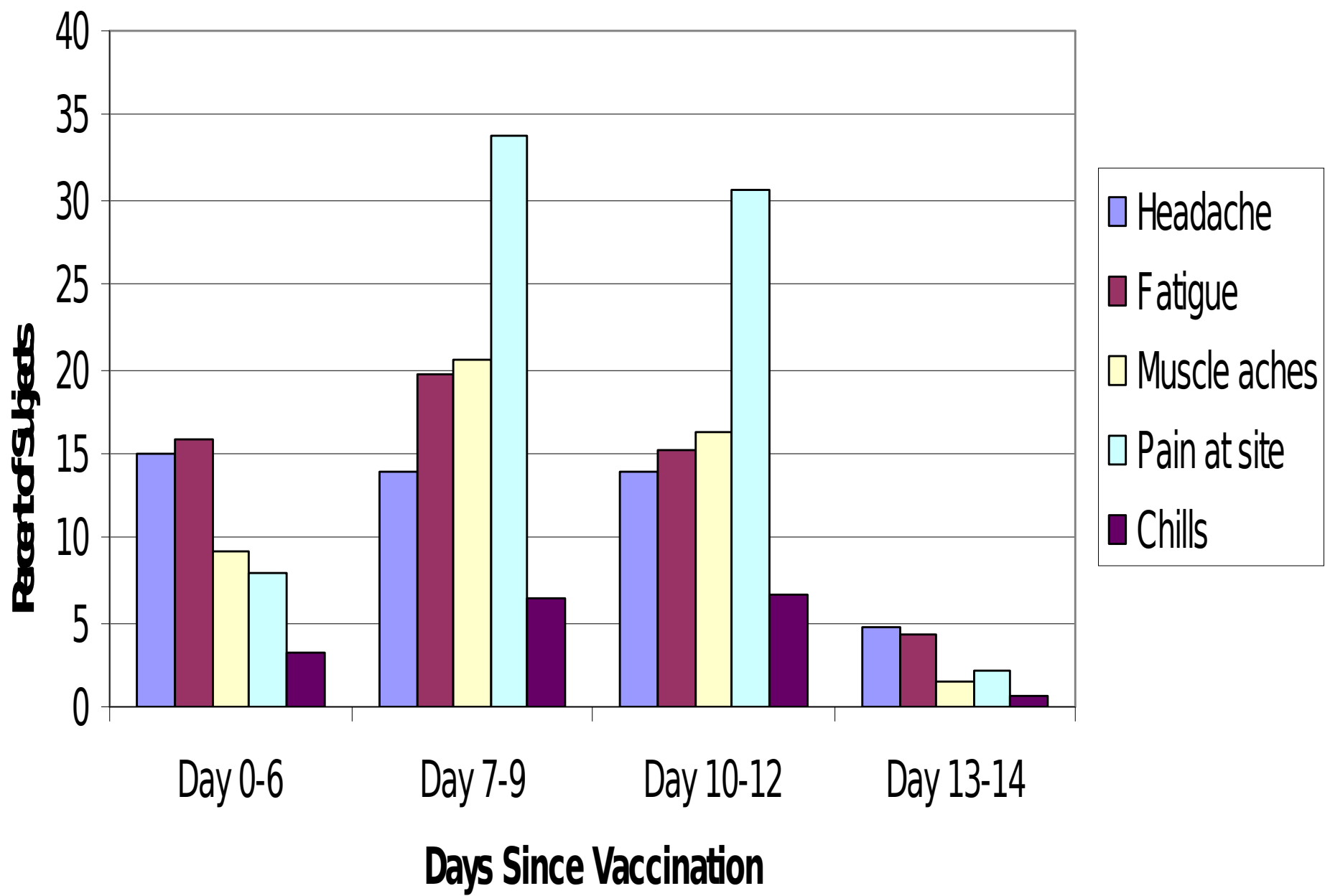
Normal Reaction



Normal with Lymphangitis



Normal with Satellite Lesions





Side Effects—Serious

- **In the past, about 1,000 out of 1,000,000 (1 million) people experienced reactions that were serious, but not life-threatening**
 - Most involved vaccine virus elsewhere on body
 - Many preventable through better *Hand Washing!*
- **From 14 to 52 people out of 1,000,000 vaccinated for first time experienced potentially life-threatening reactions**
 - 1 or 2 people of 1,000,000 may die as a result
- **Serious side effects are generally more rare after revaccination but may require prolonged care**
- **To reduce risk of side effects, exempt people with immune problems or certain skin conditions**





Serious Adverse Events

Serious reactions described on CDC smallpox website

- **Encephalitis, neurologic reactions**
- **Viral spread to eye, genital or rectal area of vaccinee or close contact**
- **Progressive or generalized vaccinia**
- **Eczema vaccinatum**
- **Vaccinia necrosum**
- **Other very rare reactions**
 - **Vaccinia infection of bone**
 - **Pericarditis**





Care of Vaccination Site

- Vaccine virus remains at the site, until scab falls off & can infect others
- **Vaccine recipients need to be careful and informed**
 - **Vaccine recipients need to educate close contacts about risk**
 1. Don't touch any vaccination site
 2. If you touch it by accident, wash your hands right away
 3. Don't let others touch vaccination site or materials that covered it
 - **Wear gloves if assisting with site care**
 4. Handle your own laundry/towels and place in hot soap water directly



This woman touched her vaccination site, then touched her eye. She recovered with a scarred eyelid.





Care of Vaccination Site

Follow these instructions carefully, or you could harm yourself or others. Ask questions if

- **Until your scab falls off, avoid spreading vaccine virus to close contacts, particularly with people exempted from getting vaccinations themselves**
- **Do not share a bed, bunk, or cot with people who are exempted from vaccination**
 - **Anyone is at risk for vaccine virus contact infection so Wash Your Hands**
- **Do not share clothes, towels, linen, or toiletries**
 - **Anyone is at risk for vaccine virus contact infection so Wash Your Hands**





Care of Vaccination Site

Follow these instructions carefully, or you could harm yourself or others. Ask questions if

- ~~Anything is unclear~~ **Wear sleeves to cover the site.**
- **Use bandages, if needed. Dispose of bandages in sealed or double plastic bags. You may carefully add bleach, alcohol or soap, if desired**
- **Keep site dry, except normal bathing. Avoid rubbing. Avoid swimming or public bathing facilities**
- **Laundry clothing, towels, and sheets in hot water with detergent or bleach.**
- **When the scab falls off, flush it down the toilet (alcohol, sunlight, bleach kills the virus).**
- **Wash your hands - Hand washing, hand washing!**





Exemptions to Vaccination

Medical exemptions are indicated if a medical condition exists that increases the risk of serious adverse events.

- **Some people should not get smallpox vaccine, except under emergency situations. A Medical Exemption is indicated IF**

- Your immune system is not working fully (due to disease, medication, or radiation)
- You have or had eczema or atopic dermatitis
 - Red, itchy, scaling chronic rashes that come and go
- You have active skin diseases like
 - Burns, psoriasis, contact dermatitis, chickenpox, shingles, impetigo, uncontrolled acne, 'til it clears up
- You are pregnant or breastfeeding
- You have a close contact with the above risk factors

You are allergic to a prior dose of the vaccine or a component such as latex or several antibiotics



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Pregnancy & Infant Care

Infants < 1 year of age are relatively immune deficient and may be at increased risk for vaccine complications

- **Defer routine smallpox vaccinations until after**
 - Pregnancy
 - Breastfeeding
 - After infancy unless alternative care option is available
- **When pregnant women get smallpox vaccine, pregnancy usually goes well**
- **On rare occasions, vaccine virus has caused vaccinia infection of the fetus**
- **Minimize close contact with infants and children and ALWAYS wash hands before handling infant or child**



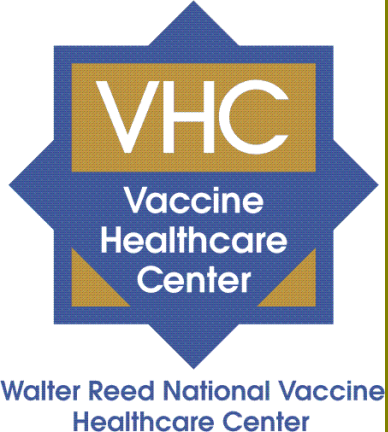


Vaccine Safety

4. Proper screening for vaccine contraindications is critical to the success of smallpox

- **Read the screening questionnaire carefully**
- **Ask questions if you are unsure**
- **Contact family members who may know about childhood history of recurrent rashes like eczema**
- **Talk to close contacts and family members about the vaccination program and safety precautions**
- **Ask for assistance at any point if needed by you or your close contacts**
- **If you have safety concerns or need additional consultation with your primary care provider, please indicate this need prior to receiving the vaccine.**





What if risk factors for serious reactions are identified after vaccination?

Examples of important screening history

- **Childhood eczema**
- **HIV infection**
- **Pregnancy**
- **Immune deficiency**
- **Drugs that suppress immune system**

Recommendations

- **Majority of patients with these problems did NOT have a serious problem**
- **Contact your provider for close follow-up**



Vaccines

5. Preserving the health and safety of our people are our top concerns

Vaccines will

- **Keep you and your team healthy**
- **Support the readiness missions by**
 - **Shielding you from dangerous germs**
 - **Keeping units fit to fight**
 - **Helping you return home safely**

Vaccines saved more lives than any other medical invention, more than antibiotics or surgery.

- **Only clean water & toilets has saved more lives**



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Adverse Event Reporting

- Vaccine Adverse Event Reporting System (VAERS)
 - **FDA and CDC review 100% of adverse-event reports submitted to VAERS**
 - **Anyone can submit a VAERS form, online preferred**
- DoD requires a VAERS form submission for:
 - **Loss of duty 24 hours or longer (≥ 1 duty day)**
 - **Hospitalization**
 - **Suspected vaccine vial contamination**
 - Other submissions encouraged
- Report to VAERS at www.vaers.org or call 800-822-7967
- Vaccine Healthcare Center (VHC) Network for support of serious or prolonged adverse events case management, registry functions & VAERS preparation assistance:



Ask VHC@amedd.army.mil or via www.VHCInfo.org

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Reserve Adverse-Event Care

Access to health care for all vaccine recipients

- **Adverse events after DoD- or USCG-directed vaccinations are line-of-duty conditions**
- **Someone with an adverse event in a non-duty status possibly associated to any vaccination:**
 - Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
 - Report the event to your unit commander or designated representative as soon as possible
 - See local medical department or squadron for guidance and assistance
 - Commander will determine Line of Duty and/or Notice of Eligibility status, if required





Materials Provided

DoD Commitment to Quality in Smallpox Vaccination Program Education and

Screening

- **Trifold Information: “WHAT YOU NEED TO KNOW ABOUT SMALLPOX VACCINE”**
 - Side effects to be expected with the vaccine
 - Importance of preventing vaccine virus spread to other parts of the body or contacts
 - Care of vaccination site and hand washing
- **Education about the importance of proper screening for vaccine contraindications and precautions**





Information Sources

- Chain of Command
- Website: www.vaccines.army.mil
- E-Mail: vaccines@amedd.army.mil
- Toll-Free: 877.GET.VACC
- CDC National Immunization Hotline: 800.232.2522
- CDC Bioterrorism Information: www.bt.cdc.gov
- Walter Reed Vaccine Healthcare Center (VHC): 202.782.0411 with web-site at www.vhcinfo.org
 - Askvhc@amedd.army.mil for clinical consultation

For information on civilian health-care services outside a Military Treatment Facility:



■ Call: 888.MHS.MMSO (888.647.6676)

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